



## Complete Summary

---

### GUIDELINE TITLE

Evidence based clinical practice guideline for medical management of acute otitis media in children 2 months to 13 years of age.

### BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for medical management of acute otitis media in children 2 months to 13 years of age. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2004 Oct. 16 p. [113 references]

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Cincinnati Children's Hospital Medical Center. Evidence-based clinical practice guideline for medical management of otitis media in children 2 months to 6 years of age. Cincinnati (OH): Children's Hospital Medical Center (CHMC); 1999. 8 p.

### \*\* REGULATORY ALERT \*\*

### FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, the U.S. Food and Drug Administration (FDA) asked manufacturers of non-prescription (over the counter [OTC]) non-steroidal anti-inflammatory drugs (NSAIDs) to revise their labeling to include more specific information about potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drugs. See the [FDA Web site](#) for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all NSAIDs make labeling changes to their products. FDA recommended proposed labeling for both the prescription and OTC NSAIDs and a medication guide for the entire class of prescription products. See the [FDA Web site](#) for more information.

Note from the National Guideline Clearinghouse and the Cincinnati Children's Hospital Medical Center: The guideline developers have reviewed the above-mentioned FDA advisories and believe that the mention of ibuprofen to

alleviate acute fever and pain associated with acute otitis media in children is appropriate as recommended in this guideline.

## COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

CONTRAINDICATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

## SCOPE

### DISEASE/CONDITION(S)

Acute otitis media (AOM)

### GUIDELINE CATEGORY

Counseling

Diagnosis

Evaluation

Management

Treatment

### CLINICAL SPECIALTY

Emergency Medicine

Family Practice

Otolaryngology

Pediatrics

### INTENDED USERS

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Patients

Physician Assistants

Physicians

### GUIDELINE OBJECTIVE(S)

- To improve the use of appropriate diagnostic criteria
- To improve the use of appropriate antibiotic therapy
- To improve symptom relief
- To avoid medical complications
- To improve parental involvement in decision-making around the management of acute otitis media

## TARGET POPULATION

Children age 2 months up to 13 years of age who present with signs and symptoms of acute otitis media (AOM)

Note: Children with comorbid conditions increasing the risk or severity of otitis media, including immunodeficiencies, craniofacial or neurologic abnormalities, or sensory deficits are excluded. Children with pressure equalization (PE) tubes in place are also excluded.

## INTERVENTIONS AND PRACTICES CONSIDERED

### Diagnosis

1. History and physical examination
2. Pneumatic otoscopy and tympanometry
3. Acoustic reflectometry

### Management/Treatment

1. Appropriate analgesia including oral agents (acetaminophen or ibuprofen) or topical ear drops (anesthetic or Naturopathic Herbal Extract Ear Drops)
2. Antibiotic therapy
  - Amoxicillin (first-line treatment)
  - Amoxicillin/clavulanate [Augmentin®]
  - Cephalosporins, including cefdinir (Omnicef®), cefprozil [Cefzil], cefuroxime (Ceftin®), and ceftriaxone (Rocephin®)
  - Macrolides/azilides, including azithromycin (Zithromax®) and clarithromycin (Biaxin®)
3. Observation option with or without safety net antibiotic prescription
4. Steroids, antihistamines, decongestants, and complementary or alternative therapies (considered, but not recommended)
5. Follow-up evaluation

### Consults and Referrals

1. Referral for an audiologic evaluation
2. Referral for an otolaryngological evaluation

### Education

1. Educating family on the natural history of acute otitis media and middle ear effusion, signs and symptoms of clinical deterioration, and appropriate follow-up

2. Educating family on preventable and nonpreventable risk factors

## MAJOR OUTCOMES CONSIDERED

- Duration of signs and symptoms of acute otitis media (fever, discomfort)
- Risk of disease recurrence
- Hearing or speech compromise or subsequent need for insertion of tympanostomy tubes

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

To select evidence for critical appraisal by the group, the citations in the American Academy of Pediatrics (AAP) Clinical Practice Guideline for Acute Otitis Media were reviewed. Additionally, the Medline, EmBase, and the Cochrane databases were searched for dates of January, 2003 through June, 2004 to generate an unrefined, combined evidence database using a search strategy focused on answering clinical questions relevant to otitis media and employing a combination of Boolean searching on human-indexed thesaurus terms (Medical Subject Headings (MeSH) headings using an OVID Medline interface) and natural language searching on words in the title, abstract, and indexing terms. The citations were reduced by: eliminating duplicates, review articles, non-English articles, and adult articles. The resulting abstracts were reviewed by a methodologist to eliminate low quality and irrelevant citations. During the course of the guideline development, additional clinical questions were generated and subjected to the search process.

### NUMBER OF SOURCE DOCUMENTS

385

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

### METHODS USED TO ANALYZE THE EVIDENCE

Review  
Review of Published Meta-Analyses  
Systematic Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The recommendations contained in this guideline were formulated by an interdisciplinary working group which performed systematic and critical literature reviews, using the grading scale below under "Type of Evidence Supporting the Recommendations," and examined current local clinical practices.

During formulation of these guidelines, the team members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues by consensus where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups  
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines have been reviewed and approved by clinical experts not involved in the development process, senior management, Risk Management & Corporate Compliance, the Institutional Review Board, other appropriate hospital committees, and other individuals as appropriate to their intended purposes.

## RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

Each recommendation is followed by evidence grades (A-X) identifying the type of supporting evidence. Definitions for the types of evidence are presented at the end of the "Major Recommendations" field.

## Assessment and Diagnosis

### General

Signs and symptoms of acute otitis media (AOM) are often nonspecific and overlap with those of upper respiratory infections. Clinical diagnosis is especially less reliable in the child under 2 years of age. This contributes to difficulty in accurately diagnosing AOM and in evaluating results of clinical trials (Dagan et al., 2002 [S]; Froom et al., 1990 [O]; Wald, 2003 [E]).

Note: In a chart review, only 38% of pediatricians diagnoses of AOM met the Center for Disease Control (CDC) criteria for the diagnosis (Garbutt, Jeffe, & Shackelford, 2003 [O]). Inter-rater agreement for AOM diagnosis has been measured at 64% (Blomgren & Pitkaranta, 2003 [C]).

### History and Physical Examination

1. It is recommended that the components to assess for AOM in the history and physical include history of acute onset of symptoms, presence of middle ear effusion (MEE), and signs and symptoms of middle ear inflammation (American Academy of Pediatrics [AAP] Subcommittee, 2004 [S]). See table below entitled "Requirements for Diagnosis of AOM."

Note 1: Accurate diagnosis of AOM, critical to the management decision, is a competency that may be improved with specific training (Rosenfeld, 2002 [O]; Steinbach & Sectish, 2002 [O]; Pichichero & Poole, 2001 [O]). See CD-ROM available in Pratt Library (Wald & Hoberman, 2002 [E]) and an interactive case module on-line with the AAP (<http://www.aap.org/otitismedia/www/>).

Note 2: A bulging, cloudy, immobile and distinctly red tympanic membrane (TM) is most helpful in the diagnosis of AOM (Rothman, Owens, & Simel, 2003 [M]; Leibovitz et al., "Can acute otitis media," 2003 [C]; Karma et al., 1989 [D]). See table below entitled "Likelihood Ratios (LR) for Clinical Signs."

Note 3: A parental report of AOM symptoms is somewhat reliable (sensitivity 71%, specificity 80%, positive predictive value 51%, likelihood ratio [LR] 3.55) (Kontiohari et al., 1998 [C]).

Note 4: Nonspecific symptoms include cough, rhinitis, poor appetite and vomiting and have likelihood ratios (LR) near 1.0 (Heikkinen & Ruuskanen, 1995 [C], Niemela et al., 1994 [C]).

Table: Requirements for Diagnosis of AOM

|                                                                                                                                                                                                                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. History of acute onset of signs and symptoms                                                                                                                                                                                                |
| 2. Presence of MEE indicated by one of the following: <ul style="list-style-type: none"> <li>• Bulging tympanic membrane (ear drum)</li> <li>• Decreased mobility of tympanic membrane</li> <li>• Discharge from the ear (otorrhea)</li> </ul> |
| 3. Signs and symptoms of middle ear inflammation indicated by either: <ul style="list-style-type: none"> <li>• Red tympanic membrane or</li> <li>• Discomfort affecting normal activity and/or sleep (earache, otalgia)</li> </ul>             |

(AAP Subcommittee, 2004 [S])

Table: Likelihood Ratios (LR) for Clinical Signs\*

| Sign of tympanic membrane    | Positive LR (95% Confidence Interval [CI]) ** |
|------------------------------|-----------------------------------------------|
| Bulging                      | 51 (36-73)                                    |
| Cloudy                       | 34 (28-42)                                    |
| Distinctly impaired mobility | 31 (26-37)                                    |
| Distinctly red               | 8.4 (6.7-11)                                  |
| Normal color                 | 0.2 (0.19-0.21)                               |
| Normal mobility              | 0.2 (0.19-0.21)                               |

(Rothman, Owens, & Simel, 2003 [M]; Karma et al., 1989 [D])

\*Likelihood ratios quantify the change in probability of AOM when a given sign or symptom is present in a specific clinical case and depend upon a starting estimate of probability. For more information, see Appendix 2 of the original guideline document for definition and use of likelihood ratios.

\*\*95% Confidence Interval expresses the uncertainty (precision) of a measured value; it is the range of values within which we can be 95% sure that the true value lies. A study with a larger sample will generate more precise measurements, resulting in a narrower confidence interval.

2. It is recommended that pneumatic otoscopy and/or tympanometry be used to enhance accuracy when diagnosing AOM (Spiro et al., 2004 [A]; Karma et al., 1989 [D]; Brookhouser, 1998 [S]; Pelton, 1998 [S]; Jones & Kaleida, 2003 [O]; Pichichero, 2002 [O]; Pichichero & Poole, 2001 [O]).

Note 1: Pneumatic otoscopy and tympanometry measure the degree of mobility of the tympanic membrane as an indication of the presence of MEE (Jerger, 1970 [C]; Jones & Kaleida, 2003 [O]; Pichichero, 2002 [O]; Pichichero & Poole, 2001 [O]). A large, randomized controlled trial demonstrated that the appropriate use of tympanometry would reduce otitis media diagnoses by 14 to 40% (Spiro et al., 2004 [A]).

Note 2: Acoustic reflectometry is not often used nor readily available in the Cincinnati area, though the procedure is acceptable for determining the presence of MEE (Block et al., 1999 [C]; Barnett et al., 1998 [C]; Block et al., 1998 [C]; Kimball, 1998 [S]).

3. It is recommended that ear pain (otalgia) be assessed, as determined by discomfort affecting normal activity and/or sleep (Kontiohari et al., 1998 [C]; "The assessment and management," 2001 [S]).
4. It is recommended that, for patients with recurrent AOM, additional attention be paid to parental concerns about hearing loss, speech delay, or language delay (Roberts, Rosenfeld, & Zeisel, 2004 [M]).

## Management

### General

AOM is a disease with a high spontaneous resolution rate (78 to 80% resolve within 7 to 14 days), and routine antibiotic therapy of all children with suspected AOM results in the treatment of many children in whom there may be either modest benefit and/or modest adverse outcomes from antibiotic therapy (Glasziou et al., 2003 [M]; Marcy et al., 2001 [M]; Rosenfeld et al., 1994 [M]; Dowell et al., "Otitis media," 1998 [S]). Moreover, the decision to use antibiotics and the specific choice of antibiotics must take into account the increasing emergence of bacterial resistance (Doern et al, 1998 [C]; Jacobs et al, 2003 [O]; Mason et al., 2003 [O]).

Note: AOM may have potentially serious complications including mastoiditis, meningitis, and intracranial abscess formation. There is an increased incidence of mastoiditis in some countries which limit use of antibiotics for AOM, but a causal relationship is not fully supported by these data. Prevalence of mastoiditis in the U.S. is 0.4%, and 2,500 cases of AOM would need to be treated with antibiotics to prevent one case of mastoiditis (number needed to treat [NNT] = 2,500) (Van Zuijlen et al., 2001 [O]).

### Treatment



1. It is recommended that all children with AOM who have a positive assessment for pain be treated with an appropriate analgesic (AAP Subcommittee, 2004 [S]; "The assessment and management," 2001 [S]).

Note 1: Ear pain in AOM is self-limiting and time is the greatest factor in pain reduction (Sarrell, Cohen, & Kahan, 2003 [A]). Therefore, the immediate availability of a safe and effective analgesic is more important than which agent is used. These include oral agents (acetaminophen or ibuprofen) or topical ear drops (anesthetic or Naturopathic Herbal Extract Ear Drops) (Perrott et al., 2004 [M]; Sarrell, Cohen, & Kahan, 2003 [A]; Sarrell, Mandelberg, & Cohen, 2001 [A]; Bertin et al., 1996 [A]; Hoberman et al., "Efficacy of Auralgan," 1997 [B]; "The assessment and management," 2001 [S]).

Note 2: In patients with a perforated eardrum and/or discharge from the ear, avoid topical analgesic ear drops as their use will likely result in severe dizziness and vomiting.

2. It is recommended that treatment with a 10-day course of antibiotics be given to children less than 2 years of age with AOM (Cohen et al., 2000 [A], 1998 [A]; AAP Subcommittee, 2004 [S]).

Amoxicillin, in the dose range of 80 to 90 mg/kg/day is effective in the treatment of a first episode of AOM or for a recurrence more than 1 month since recovery from a prior episode of AOM (Rosenfeld et al., 1994 [M]; Piglansky et al., 2003 [C]; AAP Subcommittee, 2004 [S]). See table below entitled "First-Line Antibiotic Medication and Doses" for doses for this first-line therapy. In cases when the clinician has a high suspicion for concurrent conjunctivitis-otitis media syndrome, commonly caused by a beta-lactamase producing organism, it is reasonable to consider a second-line antibiotic (Wald, 1997 [S]).

For children with allergies to penicillin, or other reasons to consider alternative antibiotics, consider a second-line antibiotic. In a child less than 1 year of age with a history of a penicillin allergy, a careful review of the reported reaction is prudent. See extended list of antibiotic options, doses, and preparations in Appendix 3 (Rosenfeld et al., 1994 [M]).

Note: While it is suggested in general that children under two years of age with AOM be treated with antibiotics, it is recognized that in certain situations observation without antibiotics or with a safety-net antibiotic prescription (SNAP) may be reasonable. See table below entitled "Safety-Net Antibiotic Prescription (SNAP) Definition and Management" for SNAP definition. Local data suggest that the relapse/recurrent rate (defined in the study as a new case of AOM occurring between 7 and 60 days from initial episode) is about 3 times higher in children less than 2 years of age (34% compared to 10%) (Siegel et al., 2004 [C]). If observation or SNAP is utilized, both the clinician and the parents are advised to be aware of the higher relapse/recurrence rate in this age group, and close follow-up must be assured (Siegel et al., 2003 [C]).

Table: First-Line Antibiotic Medication and Doses

| Antibiotic  | Dose and frequency                                                                                                                                                      | Max Daily Dose |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| amoxicillin | <p>80-90 mg/kg per day, divided</p> <ul style="list-style-type: none"> <li>• 40-45 mg/kg twice a day (BID) or</li> <li>• 25-30 mg/kg three times a day (TID)</li> </ul> | 2 grams/day    |

Table: Safety-Net Antibiotic Prescription (SNAP) Definition and Management

|                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• SNAP is a prescription for an appropriate antibiotic, as determined by the practitioner, <u>written to be filled only within 5 days of the office visit.</u></li> </ul>                  |
| <ul style="list-style-type: none"> <li>• Instruct the parent not to fill SNAP unless symptoms worsen at any time or unless symptoms do not improve during a waiting period of 48-72 hours.</li> </ul>                             |
| <ul style="list-style-type: none"> <li>• Instruct the parent that a well-appearing child diagnosed with AOM may quickly progress to a more severe case, and to call and/or follow-up with practitioner if this occurs.</li> </ul> |

(Siegel et al., 2003 [C])

- It is recommended that in children over age 2 years with AOM and who are well-appearing, that the treatment options be discussed with the family and that the family be involved in the decision making. The options include:
  - Treatment with a SNAP to be filled after 48 to 72 hours if symptoms do not resolve with observation. See table above for SNAP definition and management.
  - Treatment with a 5-day course of antibiotics (see treatment recommendation 2 and table above entitled "First-Line Antibiotic Medication and Doses" for discussion of antibiotic selection and doses)

Note 1: There is inadequate evidence to say that antibiotic therapy is or is not beneficial to most children with AOM (Wald, 2003 [E]).

Note 2: No antibiotic prescription, with follow-up within 48 to 72 hours, is also an option in the specific case when a practitioner would like to control the observation option more closely.

Note 3: An [observation option information sheet](#) for parents is available for use through the Cincinnati Children's Hospital Medical

Center (CCHMC) Health Topics Web site (New York Regional Otitis Project, 2002 [X]; Rosenfeld, 2001 [X]).

Note 4: Parental involvement in the decision to use antibiotic therapy and the use of SNAP with pain control are effective in reducing the use of antibiotics (Pshetizky, Naimer, & Shvartzman, 2003 [B]; Siegel et al., 2003 [C]).

Note 5: In a Cincinnati office-based study, the relapse/recurrence rate for all ages (new case of AOM occurring between 7 to 60 days from initial episode) was 24% in those that filled the SNAP, compared to 11% in those that did not fill the SNAP,  $p < 0.025$  (Siegel et al., 2004 [C]).

4. It is recommended that children over age 2 years with AOM and with severe illness (see table below entitled "Factors to Consider for AOM Treatment") be treated with a 5-day course of antibiotics (see treatment recommendation 2 and table above entitled "First Line Antibiotic Medication and Doses") (Kozyrskyj et al., 2000 [M], 1998 [M]).
5. It is recommended, for a child with a recurrence of AOM in less than 1 month from completion of antibiotic therapy from a prior episode of AOM, or for a child who has recently been on antibiotics for other reasons, that antibiotic choices other than amoxicillin be considered (Leibovitz et al., "Recurrent acute otitis media," 2003 [C]; Carlin et al., 1987 [C]; Dowell et al., "Principles of judicious use," 1998 [S]; Klein, 1998 [S]). For extended list of antibiotic options, doses, and preparations, see Appendix 3 of the original guideline document entitled "Expanded Table of Antibiotic Options, Doses and Preparations."

Note: There is no strong evidence to support prolonged or prophylactic antibiotic therapy in recurring AOM (Williams et al., 1993 [M]; Koivunen et al., 2004 [A]). Persistent MEE is common, and parents may be counseled to expect fluid to take several weeks to months to clear (Rosenfeld & Kay, 2003 [M]; AAP Subcommittee, 2004 [S]).

6. It is not recommended that other therapies be used in the treatment of AOM (AAP Subcommittee, 2004 [S]).

Note 1: Steroids, antihistamines, decongestants, and complementary or alternative treatments have not been documented to be efficacious in the treatment of AOM (Butler & Van Der Voort, 2002 [M]; Flynn, Griffin, & Tudiver, 2002 [M]; Barnett et al., 2000 [C]; AAP Subcommittee, 2004 [S]). Antihistamines may prolong the duration of MEE.

Note 2: Median duration of MEE was 73 days for patients on antihistamine compared to 25 days for patients on placebo ( $p = 0.04$ ) in a randomized controlled study (Chonmaitree et al., 2003 [A]).

Note 3: It is recognized that use of complementary and alternative medicine (CAM) is common and its use is often not reported to the primary care physician (PCP) (Eisenberg et al., 1998 [O]; Spiegelblatt, 1994 [O]). The primary care physician may take the AOM visit as an opportunity to begin a

respectful discussion regarding the safety and efficacy of complementary and alternative medicine with families who report its use.

Table: Factors to Consider for AOM Treatment

|                                                                                                                                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• Temperature &gt;38.6 degrees C (101.5 degrees F) in the past 48 hours</li></ul>                                                    |
| <ul style="list-style-type: none"><li>• Symptoms suggestive of AOM for &gt;48 hours</li></ul>                                                                              |
| <ul style="list-style-type: none"><li>• Toxic appearance</li></ul>                                                                                                         |
| <ul style="list-style-type: none"><li>• Tympanic membrane of the infected ear not intact</li></ul>                                                                         |
| <ul style="list-style-type: none"><li>• Another episode of AOM within past 3 months</li></ul>                                                                              |
| <ul style="list-style-type: none"><li>• Signs of impending perforation in the infected ear as judged by examining clinician</li></ul>                                      |
| <ul style="list-style-type: none"><li>• A coexisting bacterial infection</li></ul>                                                                                         |
| <ul style="list-style-type: none"><li>• Concerns of clinician that the family would be unable to seek medical care if the child's clinical status were to worsen</li></ul> |
| <ul style="list-style-type: none"><li>• Concerns of caregiver or clinician that the caregiver could not gain an acceptable understanding of the therapeutic plan</li></ul> |

#### Follow-up: to Treatment and Observation Options

7. It is recommended, for the first or a sporadic episode of AOM, that when the initial management approach fails, the clinician reevaluate the antibiotic decision.

If symptoms worsen at any time or if symptoms do not improve during a waiting period of 48 to 72 hours of initial presentation with AOM, and reexamination continues to suggest that AOM is the appropriate diagnosis, then start amoxicillin if not already initiated or change to an alternative antibiotic if the child is already on a first line drug.

Note: Options for alternative antibiotics include:

- Amoxicillin/clavulanate: efficacy has been shown for AOM and may be used when resistance is likely (Hoberman et al., Equivalent efficacy, 1997 [A]; Dagan et al., 2001 [C])
- Ceftriaxone intramuscularly (IM): 3 consecutive daily doses is efficacious in nonresponsive AOM for children with vomiting or otherwise unable to tolerate oral dosing (Leibovitz et al., 2000 [A]).

For children with allergies to penicillin, or other reasons to consider another antibiotic choice, see extended list of antibiotic options, doses, and preparations in Appendix 3 of the original guideline document.

8. It is recommended that the clinician reevaluate the patient in 4 to 8 weeks after diagnosis, depending on existing risk factors, to document resolution or persistence of effusion (AAP Subcommittee, 2004 [S]; Local Expert Consensus [E]).

### Consults and Referrals

1. It is recommended that a practitioner have a low threshold for referral for an audiologic evaluation by a pediatric audiologist if concerns around hearing, speech, or language are raised by parents, clinician, or other caregivers because of recurrent AOM (Mandel et al., 1991 [A]; Hsu, Levine, & Giebink, 1998 [C]; Teele et al., 1990 [C]; Bachmann & Arvedson 1998 [S]).
2. It is recommended that a child be referred for an otolaryngological evaluation for:
  - Recurrent AOM (history of 6 episodes over a 12-month period taking into account the severity of episodes, clustering of episodes, and persistence of otitis media with effusion)
  - Persistent otorrhea
  - Concerns about mastoiditis, or other complications of AOM
  - Perceived need for tympanocentesis and/or myringotomy (e.g., acute episode not responsive to medical therapy)
  - Abnormal audiologic evaluation

(Froom et al., 1993 [C])

### Education

1. It is recommended that the family be educated regarding the natural history of AOM, signs and symptoms of clinical deterioration, and appropriate follow-up.
2. It is recommended that the practitioner discuss with the parent that persistent MEE is common, and parents may expect fluid to take several weeks to months to clear (Rosenfeld & Kay, 2003 [M]; AAP Subcommittee, 2004 [S]).
3. It is recommended that the family be educated about preventable risk factors. These include:
  - Exposure to others (especially family members) with upper respiratory tract infections (Uhari, Mantysaari, & Niemela, 1996 [M])

- Parental smoking or other sources of second-hand smoke (Uhari, Mantysaari, & Niemela, 1996 [M]; Ilicali et al., 1999 [C])
- Daycare attendance (Uhari, Mantysaari, & Niemela, 1996 [M]; Bradley, 2003 [C])

Note: Though daycare attendance may not be preventable, options to reduce risk of AOM include delaying daycare, selecting a setting with fewer children, and/or verifying the daycare facility's hand washing practices and availability of sinks.

- Excessive pacifier use, limiting use to when the child is falling asleep (Uhari, Mantysaari, & Niemela, 1996 [M]; Niemela et al., 2000 [A])
- Breastfeeding duration less than 3 months (Uhari, Mantysaari, & Niemela, 1996 [M])
- Bottlefeeding with the child on his/her back: assure that infants are offered bottle feedings while sitting in upright positions (Tully, Bar-Haim, & Bradley, 1995 [B])

Parents may also benefit by understanding nonpreventable risk factors or common misconceptions.

- Anatomy of the eustachian tube in young children
- It is not always known why a child gets AOM.
- Allergies do not cause AOM.

#### Definitions:

#### Evidence Based Grading Scale:

A: Randomized controlled trial: large sample  
 B: Randomized controlled trial: small sample  
 C: Prospective trial or large case series  
 D: Retrospective analysis  
 E: Expert opinion or consensus  
 F: Basic laboratory research  
 S: Review article  
 M: Meta-analysis  
 Q: Decision analysis  
 L: Legal requirement  
 O: Other evidence  
 X: No evidence

#### CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for evaluation and management of acute otitis media in children 2 months to 13 years of age.

### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for the recommendations (see "Major Recommendations").

Evidence Based Grading Scale:

- A: Randomized controlled trial: large sample
- B: Randomized controlled trial: small sample
- C: Prospective trial or large case series
- D: Retrospective analysis
- E: Expert opinion or consensus
- F: Basic laboratory research
- S: Review article
- M: Meta-analysis
- Q: Decision analysis
- L: Legal requirement
- O: Other evidence
- X: No evidence

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Effective medical management of acute otitis media in children 2 months to 13 years of age
- Improved use of appropriate diagnostic criteria
- Improved use of appropriate antibiotic therapy
- Improved symptom relief
- Avoidance of medical complications
- Improved parental involvement in decision-making around the management of acute otitis media

### POTENTIAL HARMS

Not stated

## CONTRAINDICATIONS

### CONTRAINDICATIONS

In patients with a perforated eardrum and/or discharge from the ear, avoid topical analgesic ear drops as their use will likely result in severe dizziness and vomiting.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

These recommendations result from review of literature and practices current at the time of their formulations. This protocol does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the guidelines to meet the specific and unique requirements of individual patients. Adherence to this pathway is voluntary. The physician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

Appropriate companion documents have been developed to assist in the effective dissemination and implementation of the guideline.

### IMPLEMENTATION TOOLS

Clinical Algorithm  
Patient Resources  
Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for medical management of acute otitis media in children 2 months to 13 years of age. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2004 Oct. 16 p. [113 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.



## DATE RELEASED

1999 (2004 Oct 29)

## GUIDELINE DEVELOPER(S)

Cincinnati Children's Hospital Medical Center - Hospital/Medical Center

## SOURCE(S) OF FUNDING

Cincinnati Children's Hospital Medical Center

## GUIDELINE COMMITTEE

Acute Otitis Media Team Members 2004

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Community Physicians: Stephen Pleatman, MD, Chair; Robert Siegel, MD

CCHMC Physicians and Practitioners: Kieran Phelan, MD (General Pediatrics); Mike Rutter, MD (Otolaryngology); Paul Willging, MD (Otolaryngology); Karen Zur, MD (Otolaryngology); Susan Wiley, MD (Developmental Disabilities); Stephanie Kennebeck, MD (Emergency Medicine); Rebecca Brady, MD (Infectious Diseases)

Residents: Elena Huang, MD, Chief; Derek Fletcher, MD; Sharlene Matthieu, MD

Patient Services: Michelle Widecan, RN, MSN, CPNP (Emergency Dept); Gayle Riemer, MA CCC-A (Audiology); Dawn Butler, PharmD (Pharmacy)

Parent Advisors: Melissa Kennedy; Lisa Bohman

Division of Health Policy Clinical Effectiveness Support: Eloise Clark, MPH (Facilitator); Angela Booth-Jones, PhD, MS (Sen. Outcomes Coordinator); Judy Bush, RN (Education Coordinator); Danette Stanko, MA, MPH (Epidemiologist); Pam Schoettker, MS, (Medical Writer); Kate Rich (Lead Decision Support Analyst); Carol Frese, RN (Medical Reviewer); Ed Donovan, MD (Clinical Effectiveness); Uma Kotagal, MBBS, MSc (VP, Division Director); Ed Mendez, RN, MPH (Dir. Evidence Based Practice)

All Team Members and Clinical Effectiveness support staff listed above have signed a conflict of interest declaration.

Ad hoc Advisors: Robin Cotton, MD (Otolaryngology, Director); Chris Cunha, MD (Community Pediatrician); Bridgitt C. Pauly MS CCC-SLP/A (Speech Pathology); Keith Mandel, MD (PHO); Lea Ann Lund (Resident); Michael Farrell, MD (Chief of Staff); Richard Ruddy, MD (Emergency Medicine, Director); Tom DeWitt, MD (Gen. & Community Pediatrics, Director); Mel Rutherford, Esq (VP, Legal Services); Dorine Sequist, RN (VP, Patient Services); Barbarie Hill (Pratt Library); Kim Collins (Medical Education)

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All Team Members and Clinical Effectiveness support staff have signed a conflict of interest declaration.

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Cincinnati Children's Hospital Medical Center. Evidence-based clinical practice guideline for medical management of otitis media in children 2 months to 6 years of age. Cincinnati (OH): Children's Hospital Medical Center (CHMC); 1999. 8 p.

## GUIDELINE AVAILABILITY

Electronic copies: Available from the [Cincinnati Children's Hospital Medical Center Web Site](#).

For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Children's Hospital Medical Center Health Policy and Clinical Effectiveness Department at [HPCEInfo@chmcc.org](mailto:HPCEInfo@chmcc.org).

## AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Guideline highlights. Acute otitis media age 2 months to 13 years. Cincinnati Children's Hospital Medical Center, 2004.

Electronic copies: Available from the [Cincinnati Children's Hospital Medical Center Web site](#).

## PATIENT RESOURCES

The following are available:

- Appendix 1: resources for patient/family education purpose. Cincinnati Children's Hospital Medical Center, 2004. Electronic copies available from the [Cincinnati Children's Hospital Medical Center Web site](#).
- Ear infections and acute otitis media. Cincinnati Children's Hospital Medical Center, 2004. Electronic copies available from the [Cincinnati Children's Hospital Medical Center Web site](#).
- Types of hearing tests. Cincinnati Children's Hospital Medical Center, 2004. Electronic copies available from the [Cincinnati Children's Hospital Medical Center Web site](#).
- Managing ear infections (acute otitis media). Cincinnati Children's Hospital Medical Center, 2004. Electronic copies available from the [Cincinnati Children's Hospital Medical Center Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC STATUS

This summary was completed by ECRI on September 20, 1999. The information was verified by the guideline developer as of November 15, 1999. This NGC summary was updated by ECRI on December 8, 2004. The information was verified by the guideline developer on January 12, 2005. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

## COPYRIGHT STATEMENT

This NGC summary is based on the original full-text guideline, which is subject to the following copyright restrictions:

Copies of [Cincinnati Children's Hospital Medical Center \(CCHMC\)](#) Evidence-Based Clinical Practice Guidelines (EBCG) are available online and may be distributed by any organization for the global purpose of improving child health outcomes. Examples of approved uses of CCHMC's EBCG include the following:

- Copies may be provided to anyone involved in the organization's process for developing and implementing evidence-based care guidelines.
- Hyperlinks to the CCHMC website may be placed on the organization's website.
- The EBCG may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents.
- Copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at [HPCEInfo@cchmc.org](mailto:HPCEInfo@cchmc.org) for any EBCG adopted, adapted, implemented or hyperlinked to by a given organization and/or user, is appreciated.

## DISCLAIMER

### NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion.aspx>.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2006 National Guideline Clearinghouse

Date Modified: 10/9/2006

